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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,311	09/28/2001	David E. Berg	1623-U-05	5039

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MICHAEL W. GOLTRY
340 EAST PALM LANE
SUITE 260
PHOENIX, AZ 85004

EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/966,311

Applicant(s)

BERG ET AL.

Examiner

Khatol S Shahnan-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 2-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

1. Applicants' election with out traverse of December 05, 2003 is acknowledged. Applicants elected group I, claim 1, drawn to a method for determining abnormal procoagulant factors.
2. Claims 2-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions.
3. Currently claims 1-44 are pending.
4. Claim 1 is under consideration.

Information Disclosure Statement

5. Applicants Information Disclosure Statement filed 4/07/2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. No copies of the references listed in paper # 5 have been submitted. It has been placed in the application file, but the information referred to therein has not been considered. Applicants need to provide copies of the cited missing references.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

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Claim 1 recites the limitation "the eight procoagulant factors cited ". There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the blood of a patient ". There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the coagulation response ". There is insufficient antecedent basis for this limitation in the claim.

Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

Claim 1 recites step a, it is not clear what other steps are included in this claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Berg et al. (Journal of the International Society on Thrombosis and Haemostasis, Abstract, Supp. August 1999, page 317). Applicants' prior art of record.

The claim is drawn to a method for diagnosing the presence of procoagulant genetic and metabolic factors associated with activation of coagulation response comprising testing a patient's blood sample to determine if one or more procoagulant factors are abnormal.

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Berg et al. teach a method for diagnosing the presence of procoagulant genetic and metabolic factors associated with activation of coagulation response comprising testing a patients blood sample to determine if one or more procoagulant factors is abnormal (see abstract 998 in page 317). Berg et al. tested five factors including prothrombin and antithrombin. The prior art teaches the claimed method.

Since the office does not have the facilities for examining and comparing applicants' method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i. e., that the method of prior art does not possess the same material structure and functional characteristics of the claimed method). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Vecchi et al. (International Journal Clinical Laboratory Research, Vol. 21, No.2, pp.165-170, 1991).

Applicants' prior art of record.

The claim is drawn to a method for diagnosing the presence of procoagulant genetic and metabolic factors associated with activation of coagulation response comprising testing a patient's blood sample to determine if one or more procoagulant factors are abnormal.

Vecchi et al. teach a method for diagnosing the presence of procoagulant genetic and metabolic factors associated with activation of coagulation response comprising testing a patients blood sample to determine if one or more procoagulant factors is abnormal (see abstract and page 166). Vecchi et al. tested multiple factors including prothrombin, antithrombin, protein C, protein S and plasminogen. The prior art teaches the claimed method.

Since the office does not have the facilities for examining and comparing applicants' method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i. e., that the method of prior art does not possess the same material structure and functional characteristics of the claimed method). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

11. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Kahn et al. (Canadian Medical Association Journal, Vol. 157, No.6, pp.673-681, 1997). Applicants' prior art of record.

The claim is drawn to a method for diagnosing the presence of procoagulant genetic and metabolic factors associated with activation of coagulation response comprising testing a patient's blood sample to determine if one or more procoagulant factors are abnormal.

Kahn et al. teach a method for diagnosing the presence of procoagulant genetic and metabolic factors associated with activation of coagulation response comprising testing a patients blood sample to determine if one or more procoagulant factors is abnormal (see abstract and page 675-676). Kahn et al. tested multiple factors including prothrombin, antithrombin, protein C and protein S. The prior art teaches the claimed method.

Since the office does not have the facilities for examining and comparing applicants' method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i. e., that the method of prior art does not possess the same material structure and functional characteristics of the claimed method). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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February 7, 2004



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER